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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,479	04/09/2004	Hector F. DeLuca	1256-00946	1063
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ANDRUS, SCEALES, STARKE & SAWALL, LLP 100 EAST WISCONSIN AVENUE, SUITE 1100 MILWAUKEE, WI 53202				
			EXAMINER QAZI, SABIHA NAIM	
			ART UNIT	PAPER NUMBER

1616

DATE MAILED: 11/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/821,479	<b>Applicant(s)</b> DELUCA ET AL.	
	<b>Examiner</b> Sabiha Qazi	<b>Art Unit</b> 1616	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-109 is/are pending in the application.
- 4a) Of the above claim(s) 30-109 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

### **Non-Final Action on Merits**

Acknowledgement is made of the response filed on 8/8/05. Amendments are entered. Claims 1-109 are pending. Claims 1-29 are rejected others are withdrawn from consideration as non-elected invention. No claim is allowed. Restriction is made FINAL.

#### Response to arguments

- Applicants arguments were fully considered but are not found persuasive therefore all the rejections are maintained for the same reasons as set forth in our previous office action.
- Applicants are arguing that claims structurally different from the prior art. Examiner respectfully disagrees because claims are generically taught by the prior art. There differences in claiming specific substituent in present claims. Thee same substituents have been claimed in the above cited patents.
- Since claims are obvious and are taught by the prior art one skilled in art would make and use the invention by the teachings of prior art with the expectation to use for treatment of disease such cancer, psoriasis and various other diseases.
- There is no such difference and has been argued. Applicants are requested to show that these differences in "structures" are not in '928 and '071.
- As has been mentioned earlier that Examiner will rejoin the method claims when the compounds would be allowable in a condition that they are fully supported in the specification.

- In order to advance the prosecution Applicant may consider calling the Examiner to discuss the issues surrounding this application.

### ***Double Patenting***

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 and 14-16 of U.S. Patent No. 5843928. Although the conflicting claims are not identical, they are not patentably distinct from each other

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because presently claimed invention is considered obvious over the reference. See the entire document especially the abstract, summary of invention, and claims.

3. Presently claimed invention is generically claimed by the US '928. The invention is considered obvious when X represents H, alkyl or hydroxy protecting group and US '928 when R6 and R8 represent hydroxyalkyl group. Presently claimed invention is drawn to 2-hydroxypropylidene-19-nor compounds and their derivatives. Even though none of the exemplified compounds represent hydroxy propylidene compounds as presently claimed however, claims do recite generically presently claimed compounds.

4. It would have been obvious to one skilled in the art to prepare additional beneficial compounds at the time of invention because the reference teaches such compounds.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over claims 1-9 of United States Patent No. 6,392,071 and 5,843,928 (DeLUCA et al.). Both the reference teach 2-methylene compounds which embraces presently claimed invention. See line last two lines in col. 2 and line 1 in col. 3 where R6 and R8 can be hydroxy alkyl (in US '071) and abstract, summary of invention in column 2, lines 5-65 in column 3, lines 22-67 in column 6, examples and claims (in '928).

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Instant claims differ from the reference in that they are of different generic scope. Presently claimed invention is obvious when in prior art one of R<sub>6</sub> and R<sub>8</sub> represent H, hydroxy alkyl Y<sub>1</sub> and Y<sub>2</sub> are H, and 26 and 27 are dihydro, the reference teaches all the substituents as presently claimed. Instant claims are generically taught by the prior art and would have been suggested to one skilled in the art. See the entire document especially in '928 abstract, summary of invention in column 2, lines 5-65 in column 3, lines 22-67 in column 6, examples and claims.

It had been held by Courts that the indiscriminate selection of "some" from among "many" is considered prima facie obvious. In re Lemin, 141 USPQ 814 (1964); National Distillers and Chem. Corp. V. Brenner, 156 USPQ 163.

It would have been obvious to one skilled in the art to prepare additional beneficial hydroxypropylidene vitamin D compounds as presently claimed with the expectation that it would be useful for the treatment of cancer, psoriasis and various other diseases because prior art teach hydroxyalkyl substituted on 2-methylene vitamin D (see substituent of R<sub>6</sub> and R<sub>8</sub>). Prior does not teach any specific compound in the examples or in claims however, these compounds are generically taught and therefore considered obvious.

The instant claimed compounds would have been obvious because one skilled in the art would have been motivated to prepare compounds embraced by the genus of the above cited references with the expectation of obtaining additional beneficial compounds.

One having ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested

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by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within the genus. In re Susi, 440 F.2d 442, 445, 169 USPQ 423, 425 (CCPA 1971), followed by the Federal Circuit in Merck & Co. V. Biocraft Laboratories, 874 F.2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir. 1989).

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

#### **Contact Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SABIHA QAZI, PH.D  
PRIMARY EXAMINER